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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|-----------------------------|------------------------|
| 10/082,492 | 02/22/2002 | Gene Samson | 1001.1763103 | 4234 |
| 28075 7590 11/14/2007 CROMPTON, SEAGER & TUFTE, LLC 1221 NICOLLET AVENUE SUITE 800 MINNEAPOLIS, MN 55403-2420 | | | EXAMINER ARAJ, MICHAEL J | |
| | | | ART UNIT 3733 | PAPER NUMBER |
| | | | MAIL DATE 11/14/2007 | DELIVERY MODE PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/082,492 | Applicant(s) SAMSON ET AL. | |
| | Examiner Michael J. Araj | Art Unit 3733 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 31, 2007 has been entered.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

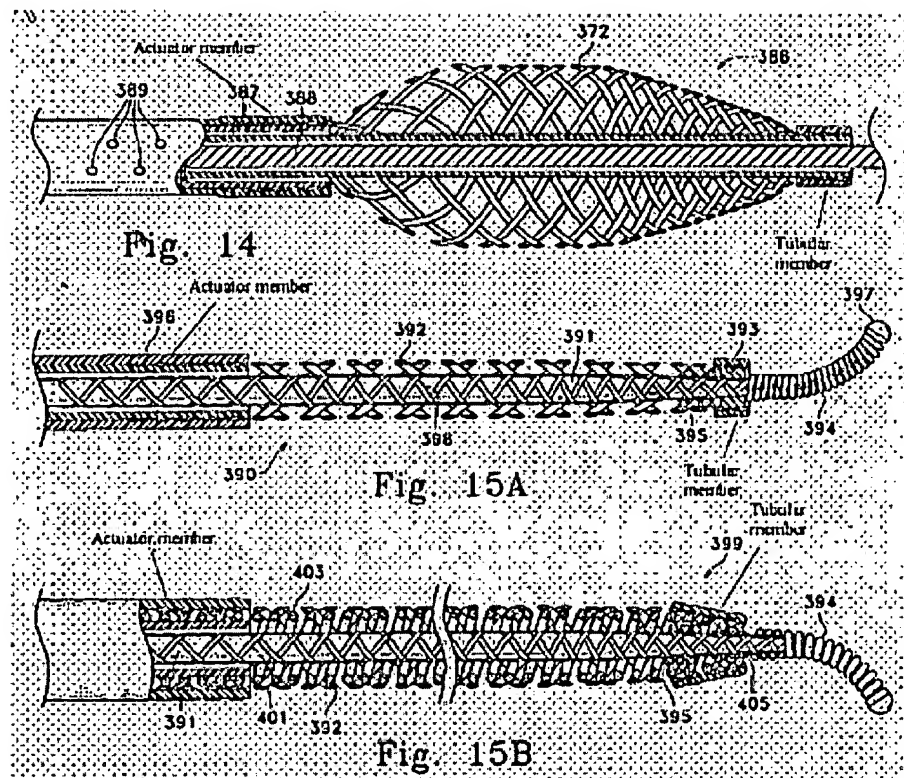
Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21, 22 and 24-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Engelson et al. (U.S. Patent No. 5,972,019) in view of Ginsburg (U.S. Patent No. 5,011,488).

Engelson et al. disclose a device comprising a core wire, e.g. 388 01- 391 with a coil tip coupled to a distal end of the core wire (see for example Figures 14, 15A, 15B). The device further comprises a cage, e.g. 372 or 392. The cage has a distal end, proximal end, first deployment shape, and a second expanded shape. The first and second shapes are different from each other. The device further has a tubular member (see Figures 14, 15A, and 15B) coupled to a distal end of the cage assembly and the tubular member surrounds a distal portion of the core wire proximal to the coil tip.



The device also has an actuator member, as shown above, that has a first position and a second position, and is located proximally to the cage and substantially coaxial about the core wire. When the actuator member is in a first position the cage is in a deployment shape and when the actuator member is in the other position, the cage is in the second expanded shape. The core wire is freely moveably axially through the cage assembly (see col.13, lines 43-44). The tubular member can be considered a bushing. The device can further include an inner coil, e.g. 401, surrounding the core wire within the cage assembly. The inner coil inner coil does not pass distally on the core wire. Engelson et al. disclose the claimed invention except for a cage assembly including a proximal cage and a distal cage.

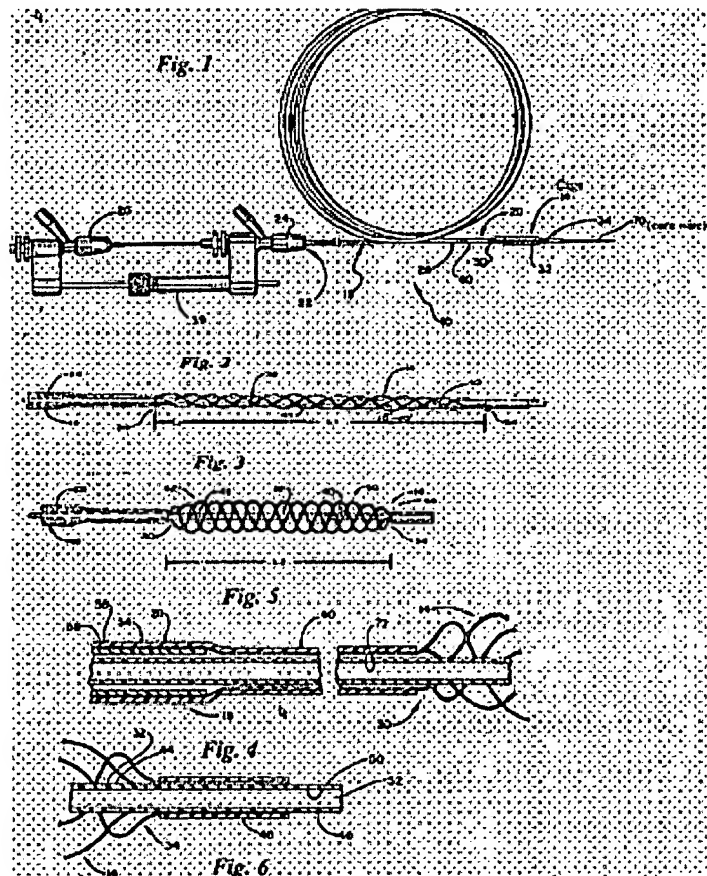
Engelson discloses the claimed invention except for the use of a proximal and distal cage. Ginsburg discloses the use of a proximal and distal element (balloon) in order to remove the thrombotic material without surgical intervention (Col. 7, lines 12-15). It would have been obvious to one skilled in the art at the time the invention was made to construct the device in Engelson with a proximal and distal cage in view of Ginsburg, in order to have a less extensive procedure.

Claims 21-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmaltz et al. (U.S. Patent No. 5,449,372 cited by applicant) in view of Ginsburg (U.S. Patent No. 5,011,488) further in view of Crittenden et al. (U.S. Patent No. 4,719,924).

Schmaltz et al. disclose a device comprising a core wire or guidewire 70, a cage 14, a tubular member 46, and an actuator element 18 (see Figures 1-5 below). The cage 14 has a distal end, proximal end, first deployment shape, and second expanded shape, wherein the shapes are different from each other (see Figures 2 and 3 below). The tubular member 46 is coupled to the distal end of the cage assembly and it would surround a distal portion of the core wire or guide wire (see Figures 1 and 6 below). The actuator element has first and second positions and it is located proximal to the cage and it is substantially coaxial about the core wire (see Figure 1). The core wire or guide wire is freely movable axially through the cage (see col. 8, lines 30-35). The core wire or guidewire may be a standard guidewire. The tubular member is considered a bushing and is made of a thermoplastic material, e.g. polyolefin (see col. 7, lines 15-17). The device further includes inner coils or bands, e.g. 40 and 41, made from radiopaque

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materials (see col. 6, lines 32-34 and 59-64). The inner coils or bands do not pass distally on the core wire.



Schmaltz et al. disclose the claimed invention except for a cage assembly including a proximal cage and a distal cage. Ginsburg discloses the use of a proximal and distal element (balloon) in order to remove the thrombotic material without surgical intervention (Col. 7, lines 12-15). It would have been obvious to one skilled in the art at the time the invention was made to construct the device in Schmaltz et al. with a proximal and distal cage in view of Ginsburg, in order to have a less extensive procedure.

The combination of Schmaltz et al. and Ginsburg disclose the claimed invention except for the core wire or guidewire having a coil tip at its distal end and a cage assembly including a proximal cage and a distal cage. Crittenden et al. disclose a core wire or guidewire with a coil tip at its distal end (see Figure 2). The core wire or guidewire is steerable wherein the coil tip can be adjusted without requiring removal of the guidewire from the patient (see abstract). It would have been obvious to one skill in the art at the time the invention was made to use with the device of the combination of Schmaltz et al. and Ginsburg with a core wire or guidewire that is steerable instead of one that is not in view of Crittenden et al., so that the guide wire can be adjusted without requiring removal of the guidewire when it is inserted into the patient.

Claims 32-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Engelson et al. (U.S. Patent No. 5,972,019) in view of Ginsburg (U.S. Patent No. 5,011,488) and further in view of Lefebvre (U.S. Patent No. 5,421,832).

The combination of Engelson et al. and Ginsburg, as applied to claim 21, disclose the claimed invention except for the cage including a plurality of petal shaped wires having a distal rake. Lefebvre teaches that helically twisted bands (which resemble the petal shaped wires) are more successful at stopping small blood clots than when they are not. It would have been obvious to one skilled in the art at the time the invention was made to construct the distal cage of the combination of Engelson et al. and Ginsburg with a plurality of petal shaped wires having a distal rake in view of

Lefebvre, in order to have an embolism treatment device that functions better in treating small blood clots.

Response to Arguments

Applicant's arguments filed on October 31, 2007 have been fully considered but they are not persuasive. Applicant argues that the Examiner has not established a motivation to combine reference for a *prima facie* obviousness rejection. The motivation used was in the fact that Ginsburg discloses the use of a proximal and distal element (balloon) in order to remove the thrombotic material without surgical intervention, as stated above. The use of a proximal and distal element, in this case a cage, would have been obvious to one skilled in the art at the time the invention was made to in order to have a less extensive procedure as well as to catch the thrombotic material prevent it from travel through the blood stream into undesirable location, which may cause further complications. Also note that even though Ginsburg discloses a proximal and distal "balloon" instead of a "cage" does not bear significant patentable weight. Firstly, the use of the word "cage" by itself does not give substantial patentable weight that differentiates it from "balloon" that is used. Secondly, the Ginsburg patent teaches the use of a proximal and distal element, where one breaks up the thrombosis and the other catches the thrombotic material, which is sufficient motivation for the use of a proximal and a distal cage.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael J. Araj whose telephone number is 571-272-5963. The examiner can normally be reached on M-F 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


MJA


EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER